Claims

1. A cardiac valve prosthesis comprising:

a frame and at least two flexible leaflets;

wherein the frame comprises an annular portion which, in use, is disposed substantially perpendicular to the blood flow, the frame having first and second ends, one of the ends defining at least two scalloped edge portions separated and defined by at least two posts, each leaflet being attached to the frame along a scalloped edge portion and being movable between an open and a closed position,

each of the at least two leaflets having a blood inlet side, a blood outlet side and at least one free edge, the at least two leaflets being in a closed position when fluid pressure is applied to the outlet side such that the at least one free edge of a first leaflet is urged towards the at least one free edge of a second or further leaflet, and the at least two leaflets being in an open position when fluid pressure is applied to the blood inlet side of the at least two leaflets such that the at least one free edge of the first leaflet is urged away from the at least one free edge of the second or further leaflet;

wherein in a first plane perpendicular to the blood flow axis the length of each leaflet in a circumferential direction (XY) between the posts at any position along the longitudinal axis (Z) of a post is defined by a parabolic function.

2. The cardiac valve prosthesis as claimed in claim 1 wherein the parabolic function defining the length of a leaflet in the circumferential direction (XY) between the posts at any position along the longitudinal axis (Z) of a post is defined by

$$Y_z = \left(\frac{4R}{L_z^2}\right)x.(L_z - x)$$

Wherein Y_z = Y offset at a particular co-ordinate X and Z

R = parabolic maximum

L_z = straight line distance between a first post and a second post of the frame at a height Z

x = distance from origin of post towards another post

and the length of the parabola defined by the above is determined by

$$\text{Length} = \int_0^l \sqrt{1+\left(\frac{dy}{dx}\right)^2}\,dx$$

3. The cardiac valve prosthesis as claimed in any preceding claim comprising three leaflets.

4. The cardiac valve prosthesis as claimed in any preceding claim wherein the frame is a collapsible stent.

5. The cardiac valve prosthesis as claimed in any preceding claim wherein at least one leaflet is configured to increase the length of the free edge of the leaflet relative to the length of the leaflet in the XY direction.

6. The cardiac valve prosthesis as claimed in claim 5 wherein the free edge of the leaflet is configured such that in a longitudinal direction (Z) perpendicular to the XY direction the free edge of the leaflet is parabolic.

7. A valve leaflet for use in the valve according to any one of claims 1 to 6, wherein said leaflet has first and second lateral edges each for attachment to a corresponding post, wherein the length of the leaflet in a circumferential direction (XY) between the lateral edges at any position along the lateral edge for attachment to the post is defined by a parabolic function.

8. A valve leaflet as claimed in claim 7 wherein the parabolic function is defined by

$$Y_z = \left(\frac{4R}{L_z^2}\right)x.(L_z - x)$$

Wherein Y_z = Y offset at a particular co-ordinate X and Z
R = parabolic maximum
L_z = straight line distance between a first lateral edge for attachment to a corresponding post and a second lateral edge for attachment to second corresponding post at a height Z
x = distance from origin of first corresponding post towards second corresponding post

and the length of the parabola defined by the above is determined by

$$\text{Length} = \int_0^l \sqrt{1+\left(\frac{dy}{dx}\right)^2}\,dx$$

9. A method of manufacturing a cardiac valve prosthesis wherein the method comprises;

(a) providing a forming element having at least two leaflet-forming surfaces wherein the forming surfaces are such that the length in

the circumferential direction (XY) of the leaflet-forming surface is defined by a parabolic function,

(b) engaging the forming element with a frame,

(c) applying a coating over the frame and the engaged forming element, the coating binding to the frame, the coating over the leaflet-forming surfaces forming at least two flexible leaflets, the at least two flexible leaflets having a length in the circumferential direction (XY) defined by a parabolic function and a surface contour such that, in use, when the first leaflet is in the neutral position an intersection of the first leaflet with at least one plane perpendicular to the blood flow axis forms a wave,

(d) disengaging the frame from the forming element.

10. The method as claimed in claim 9 wherein the valve is a valve according any of claims 1 to 6.

11. The method as claimed in claims 9 or 10 wherein the forming element has three leaflet-forming surfaces.

12. The method as claimed in any one of claims 9 to 11 further comprising the step of shaping a free edge of a leaflet.

13. The method according to claim 12 wherein said free edge of the leaflet is shaped to a parabola in a longitudinal direction (Z) perpendicular to the XY direction.

14. A method of designing a cardiac valve prosthesis of any of claims 1 to 6 comprising the steps,

a) providing a model of a heart valve comprising a frame and at least two flexible leaflets,

b) generating loads experienced by at least one cardiac valve leaflet in use and applying these to the model,

c) determining the stress distribution of the leaflet,

d) changing the circumferential length of the leaflet in XY for any position in Z,

e) determining the new stress distribution of the leaflet,

f) repeating steps D and E to minimise local stress concentrations in the leaflet.

15. A method as claimed in claim 14 which further includes the step of adjusting the model to account for factors which influence the stress

distribution of the leaflet during the cycling of the cardiac valve between an open and closed position.

16. A cardiac valve prosthesis as substantially herein before described with reference to one or more figures 2a, 3, 4a, 4b, 4c, 4d, 5a, 6, 7a, and 7b of the accompanying drawings.

17. A leaflet as substantially herein before described with reference to one or more figures 9a, 9b, 9c, 9d, 10 of the accompanying drawings.